UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,083	08/31/2001	Steven M. Lefkowitz	10010381-1	1180

7590 11/03/2004

EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/03/2004

Gordon Stewart
Agilent Technologies
Legal Dept., DL429
P.O. Box 7599
Loveland, CO 80537-0599

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,083	LEFKOWITZ ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-26 and 44-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-26 and 44-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's response filed 8/5/2004 is acknowledged and entered. Additionally, applicant has amended the specification filed 8/31/2004.

2. Claims 27-43 were canceled; Claims 7, and 16 were amended; and Claims 50-51 were added by the amendment filed on 10/2/2003.

3. Claims 1-6 have been canceled by the amendment filed on 3/25/03.

4. Claims 7-26, and 44-51 are pending.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 120 to US Patent Application serial no. 09/145,015, which is filed 9/1/1998, is acknowledged. However, it is noted that the decision on the petition under 37 CFR 1.78(a)(3), filed December 17, 2003, to accept an unintentionally delayed claim under 35 U.S.C. j 120 for the benefit of priority to the prior-filed nonprovisional applications set forth in the amendment filed concurrently with the instant petition is dismissed. Thus, the priority claimed under 35 U.S.C. 120 to US Patent Application serial no. 09/145,015, which is filed 9/1/1998, is denied until the petition is granted.

6. Claims 7-26, and 44-51 are treated on the merit in this Office Action.

Withdrawn Rejection

7. The rejections of claims 7-26, and 44-51 under 35 USC 112, first paragraph (This is a new matter rejection.) have been withdrawn in light of applicant's arguments, see page 6-7, filed 8/5/2004.

Maintained Rejections

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 7-26, and 44-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617; *filing date 11/12/1997*) and Bensimon et al. (US Patent 5,846,724; *filing date 01/28/1997*).

Wang et al. disclose methods and devices for rapidly screening a large number of events. The devices comprise of a microarray of bound components and the methods comprise of preparing the microarray (col. 2, lines 60-65). The method comprises modifying the surface of the solid substrate by the introduction of functionalities, which would react with the bound components (col. 3, lines 17-25 and 38-45). The functional group that is reactive to the bound components includes "for example, amino groups, activated halides, carboxyl groups, mercaptan groups, epoxides, and the like, may be provided in accordance with conventional ways. The linkages may be amides, amidines, amines, esters, ethers, thioethers, dithioethers, and the like". The bound components include nucleic acids and proteins (col. 3, lines 56-58; col. 5, lines 7-10).

The microarray comprises a plurality of different components (col. 2, lines 60-65). The method of Wang et al. further comprises assaying the microarray by detecting the signal produced using a disk scanner (col. 10, lines 16-25 and 50-62). The scanner would be connected to the computer through which the data is collected and process (col. 12, lines 59-67). Additionally with regard to claims 11-15, the type of functional group to be used for covalent bonding of the ligand to the surface of the substrate would be a choice of experimental design as evidenced by the cited prior art (col. 3, lines 38-45).

The method of Wang et al. does not expressly disclose the method step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups.

Bensimon et al. disclosed a method of making highly specific surfaces for biological reactions (Abstract; col. 3, lines 40-50). The method comprises functionalizing a support with a variety of silane derivatives that would result in a surface group with a double bond on the substrate (col. 5, lines 31-38) and directly anchoring the molecules of biological interest (col. 4, lines 5-25). The molecules of biological interest include molecules such as DNA, RNA, PNA, proteins, lipids and saccharides (col. 3, lines 44-45).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups as taught by Bensimon et al. in the method of Wang et al. One of ordinary skill in the art would have been motivated to modify the method by including the step of contacting said surface with a derivatizing

composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups in the method of Wang et al. for the advantage of providing a surface having a reactivity that is highly pH-dependent (Bensimon: col. 6, lines 50-56) since both Wang et al. and Bensimon et al. disclose a method of functionalizing the surface of the solid for direct attachment of molecule of biological interest (Wang: col. 3, lines 38-45; Bensimon: col. 3, lines 40-50).

Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Wang et al. and Bensimon et al. because the method combination would produce a sufficiently specific array of biological molecules wherein the anchoring of the biological molecules does not require specific functionalization of the biological molecule and the ability to detect the isolated target of interest in a sample with a signal to noise ratio that is independent of the number of molecules in the sample.

10. Claims 7-26 and 44-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,143,854) and Bensimon et al. (US Patent 5,677,126; *filing date 02/10/1995*).

Pirrung et al. disclose provides methods for forming predefined regions on a surface of a solid support, wherein the predefined regions are capable of immobilizing receptors (col. 8, lines 17-65; col. 30, lines 17-68). The method provides for the use of a substrate with a surface with a Linker molecule. The purpose of the linker molecules is to facilitate receptor recognition of the synthesized polymers on the substrate or a distal end of the linker molecules, a functional group. A single substrate supports comprise more than about 10 different monomer sequences that are

randomly distributed on the surface (fig. 10M; col. 24, lines 45-47). When receptors immobilized in this way have a differential affinity for one or more ligands, screenings and assays for the ligands can be conducted in the regions of the surface containing the receptors. Additionally, the attachment of the receptors to the surface of the substrate is from covalent bonding. The receptors include polynucleotides, nucleic acids, and peptides (col. 6, lines 41-59). The substrate is placed in a microscope detection apparatus for identification of locations where binding takes place (col. 4, lines 14-27).

The method of Pirrung et al. does not expressly disclose the method step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups.

Bensimon et al. disclosed a method of making highly specific surfaces for biological reactions (Abstract; col. 4, lines 13-23). The method comprises functionalizing a support with a variety of silane derivatives that would result in a surface group with a double bond on the substrate (col. 6, lines 6-13) and directly anchoring the molecules of biological interest (col. 4, lines 24-30, and 45-65). The molecules of biological interest include molecules such as DNA, RNA, PNA, proteins, lipids and saccharides (col. 4, lines 16-18).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method by including the step of contacting said surface with a derivatizing composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups as taught by Bensimon et al. in the method of Pirrung et al. One of ordinary skill in the art would have been motivated to modify the method by including the step of contacting said surface with a derivatizing

composition comprising at least a first silane having an olefin functional group to produce a substrate having a surface displaying olefin functional groups in the method of Pirrung et al. for the advantage of providing a surface having a reactivity that is highly pH-dependent (Bensimon: col. 7, lines 26-32) since both Pirrung et al. and Bensimon et al. disclose a method of functionalizing the surface of the solid for direct attachment of molecule of biological interest (Pirrung: col. 8, lines 17-65; Bensimon: col. 4, lines 13-23).

Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Pirrung et al. and Bensimon et al. because the method combination would produce a sufficiently specific array of biological molecules wherein the anchoring of the biological molecules does not require specific functionalization of the biological molecule and the ability to detect the isolated target of interest in a sample with a signal to noise ratio that is independent of the number of molecules in the sample.

Response to Arguments

11. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617; *filing date 11/12/1997*) and Bensimon et al. (US Patent 5,846,724; *filing date 01/28/1997*) for claims 7-26, and 44-51 was considered but they are not persuasive for the following reasons.

Applicant contends that the combination of Wang et al. and Bensimon et al. is not obvious over the presently claimed method because the combination of Wang et al. and Bensimon et al. teaches away from the presently claimed method for Bensimon et al. does not teach the claimed step of *"converting said olefin functional groups to ligand reactive functional*

groups that produce covalent bonds with said at least two different polymer ligands upon contact with said ligands". Thus the combination of Wang et al. and Bensimon et al. is not obvious over the presently claimed method.

Applicant's arguments are not convincing since the combination of Wang et al. and Bensimon et al. is obvious over the presently claimed method. First, Bensimon et al. do disclose the step of "*converting said olefin functional groups to ligand reactive functional groups that produce covalent bonds with said at least two different polymer ligands upon contact with said ligands*" (see col. 4, lines 15-18; col. 7, lines 26-32). Second, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus the combination of Wang et al. and Bensimon et al. is obvious over the presently claimed method.

12. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Pirrung et al. (US Patent 5,143,854) and Bensimon et al. (US Patent 5,677,126; *filing date 02/10/1995*) for claims 7-26 and 44-51 was considered but they are not persuasive for the following reasons.

Applicant contends that the combination of Pirrung et al. and Bensimon et al. is not obvious over the presently claimed method because the combination of Pirrung et al. and Bensimon et al. teaches away from the presently claimed method for Bensimon et al. does not teach the claimed step of "*converting said olefin functional groups to ligand reactive functional*

groups that produce covalent bonds with said at least two different polymer ligands upon contact with said ligands". Thus the combination of Pirrung et al. and Bensimon et al. is not obvious over the presently claimed method.

Applicant's arguments are not convincing since the combination of Pirrung et al. and Bensimon et al. is obvious over the presently claimed method. First, Bensimon et al. do disclose the step of "*converting said olefin functional groups to ligand reactive functional groups that produce covalent bonds with said at least two different polymer ligands upon contact with said ligands*" (see col. 4, lines 15-18; col. 7, lines 26-32). Second, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus the combination of Pirrung et al. and Bensimon et al. is obvious over the presently claimed method.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
October 28, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER